SEP 18 1998

NDA 19-773/S-010

Glaxo Wellcome Inc.
Five Moore Drive
P.O.Box 13358
Research Triangle Park, North Carolina 27709

Attention: John W. Morgan, Ph.D.
Associate Director, Regulatory Affairs

Dear Dr. Morgan:

Please refer to your supplemental new drug application dated May 13, 1998, received May 14, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ventolin NEBULES (albuterol sulfate) Inhalation Solution, 0.083%.

The supplement provides for a revised ADVERSE REACTIONS section. The sentence "Rare cases of supraventricular tachycardia, urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema have been reported after the use of inhaled albuterol." has been changed to "Cases of urticaria, angioedema, rash, bronchospasm, hoarseness, oropharyngeal edema, and arrhythmias (including atria1 fibrillation, supraventricular tachycardia, extrasystoles) have been reported after the use of VENTOLIN NEBULES Inhalation Solution."

In addition, the "Rx only" statement has been added according to Procedural Guidance #3, Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Modernization Act of 1997, issued in February 1998.

We note that the changes were put into effect per 21 CFR 314.70(c)(2)(i).

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research